

SEP - 2 2003

**Submitter**

AAI Pharma  
2320 Scientific Park Dr.  
Wilmington, NC 28405

Contact Name: Mr. Gary M. Haight  
Contact Telephone: (910) 254-7343  
Contact Fax: (910) 815-2337

**Device Name**

Proprietary Name: ARKIT HbA1C

K030553

Common/Usual Name: Glycated Hemoglobin In Vitro Diagnostic Device

Classification Name: Glycosylated Hemoglobin Assay (per 21 CFR section 864.7470)

**Predicate Equivalent Device**

Roche Unimate 3/Unimate 5 HbA1C, HbA1C Calibrator

510(k) Number: K952337

Product Code: LCP

Applicant: Roche Diagnostic Systems, Inc  
Branchburg Township  
1080 U.S. Highway 202  
Somerville, NJ 08876-3771

**Device Description**

The ARKIT HbA1c kit is a laboratory test kit, intended for quantitative determination of hemoglobin A1C % in blood by an enzymatic method, to monitor long-term glucose control in individuals with diabetes mellitus.

The ARKIT HbA1c kit is comprised of a Reagent 1, Reagent 2, Reagent 3 and an Hb Reagent (all of these components/materials are provided within the ARKIT HbA1c kit). It also offers an optional ARKIT HbA1C Calibrator (2 level; low and high) intended to be used as an exclusive calibrator of ARKIT HbA1c test as well as an optional ARKIT HbA1c Control, also 2 level; low and high, recommended as a control for the ARKIT test kit. The optional Calibrator and Control materials are required, but not provided within the ARKIT HbA1c kit.

Measurement of hemoglobin A1c % can be determined from the use of red blood cells or whole blood. The measurement principle of hemoglobin concentration is alkaline hematin method that is a general measurement method using Hb Reagent. However, Hb Reagent may not be used by the performance of chemistry analyzer. In this case,

hemoglobin is measured simultaneously with hemoglobin A1c by using Reagent 2 and this measurement principle is the oxyhemoglobin method that is a general measurement method.

Hemoglobin A1c in a hemolysate sample is digested proteolysis for glyated hemoglobin sites by specific protease and the product is measured by fructosyl amino acid oxidase (FAOD), peroxidase (POD) and coupler.

Erythrocytes are hemolyzed to prepare a sample. Hemoglobin is contained in the hemolyzed sample and is digested with protease and fructosyl amino acid for generates. Fructosyl amino acid oxidase acts on this fructosyl amino acid and generates hydrogen peroxide. The concentration of this hydrogen peroxide is in direct proportion to that of hemoglobin A1c in blood. Adding POD to this sample develops color by catalysis of POD. The concentration of hydrogen peroxide can be determined by measuring the concentration of the pigment. As a result, the concentration of hemoglobin A1c in blood can be determined.

### **Intended Use of Device**

For the treatment and control of diabetes, the blood sugar level is usually measured. However, for patients whose diabetic condition is unstable or whose blood sugar changes widely, within a day, measuring the blood sugar level is not always the best approach for proper treatment and control of the disease.

Because both types of information must be considered, measurement of hemoglobin A1c and blood sugar levels serves as a much more well-rounded and accurate testing method. Measurement of hemoglobin A1C correlates with the mean blood glucose during the prior two to three months and is widely accepted as a valuable indicator for long-term diabetic control.

The ARKIT HbA1c is a laboratory test intended for the quantitative determination of hemoglobin A1c % in blood by an enzymatic method to monitor long-term blood glucose control in individuals with diabetes mellitus.

The ARKIT HbA1c Calibrator is designed to be used with the ARKIT HbA1c test for the quantitative determination of HbA1c in blood.

The ARKIT HbA1c Control is designed to be used with the ARKIT HbA1c test for the quantitative determination of HbA1c in blood.

For in vitro use only.

### **Substantial Equivalence Based Upon Clinical Performance**

The performance characteristics of the ARKIT HbA1c assay were studied using the following chemistry analyzer

Device Name:	BAYER ADVIA 1650 CHEMISTRY ANALYZER (Sales name in Japan is JEOL JCA-BM9030)
Manufacturer:	BAYER CORPORATION
FDA Approval:	Listed 11/12/99
Classification:	I
Product Code:	JJE
Regulation Number:	862.2160

Though hemoglobin measurement is an independent measurement, using the Hb reagent, simultaneous hemoglobin measurements with hemoglobin A1c is also possible by the performance of the chemistry analyzer and are equal in performance, based upon the results of "Evaluation of Precision," "Method comparison and Correlation," "Linearity," and "Correlation of measurement of hemoglobin." The performance evaluation, except for the above, was studied by the hemoglobin independent measurement.

In reference to accuracy, three levels of samples were studied. Also, within run accuracy, each sample was studied twenty times within one batch.

The mean standard deviation (SD) and coefficient of variation (CV) were calculated.

In reference to between run and between days, the accuracy of each sample was studied per the NCCLS Guidelines (EP05-A; **Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline**). The mean, standard deviation and coefficient of variation were calculated.

In brief, the ARKIT HbA1C assays demonstrate excellent accuracy and precision results.

### **Method Comparison**

A method comparison study was accomplished contrasting ARKRAY's HbA1C device to the Roche UNIMATE HBA1C. The study utilized ninety-eight diabetic patient samples.

In addition to demonstrating results with HPLC in independent measurement studies of hemoglobin and simultaneous measurements of hemoglobin, study results of comparison with the predicate device in independent measurement and simultaneous measurements of hemoglobin are demonstrated. In all instances, the ARKRAY HbA1c assays yielded very close correlations in all samples, across the intended, usable range of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP - 2 2003

ARKRAY, Inc.  
c/o Mr. Gary M. Haight  
Regulatory Affairs Professional  
aai Pharma, Inc.  
2320 Scientific Park Drive  
Wilmington, NC 28405

Re: k030553  
Trade/Device Name: ARKIT Hb A1C; ARKIT Hb1C Calibrator; ARKIT Hb1C Control  
Regulation Number: 21 CFR 864.7470  
Regulation Name: Glycosylated Hemoglobin Assay  
Regulatory Class: Class II  
Product Code: LCP, JIT, JJX  
Dated: July 30, 2003  
Received: July 31, 2003

Dear Mr. Haight:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

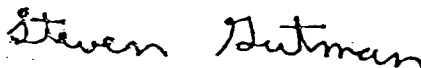
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

K030553

**Statement of Indications for Use**

ARKIT HbA1c is a laboratory test intended for the quantitative determination of hemoglobin A1c % in blood by an enzymatic method, to monitor long-term blood glucose control in individuals with diabetes mellitus.

The ARKIT HbA1c Calibrator and ARKIT HbA1c Control are designed to be used with the ARKIT HbA1c test for the determination of HbA1c in blood.

For in vitro diagnostic use only.

✓  
— prescription use

Carol Benson (n) Jean Cooper, DVM  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K030553